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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/589,862

04/30/2007

Suresh Pareek

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EXAMINER

TRAN, SUSAN T

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

09/09/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/589,862	PAREEK ET AL.	
	Examiner	Art Unit	
	SUSAN TRAN	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1-18 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1-18 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 103

Claims 1-8, 11-15 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deshpande et al. US 2004/0028737, in view of Mehra et al. US 5,733,575.

Deshpande teaches an enteric coating composition comprising methacrylate copolymer type C, polyethylene glycol 600, titanium dioxide, and talc (examples 1-4 and 8). The amounts of the above components disclosed in the examples fall within the claimed ranges, e.g., about 60% methacrylate copolymer type C, about 6% plasticizer, about 7% opacifier, and about 24% detackifier.

Deshpande does not expressly teach that the coating composition is in powder form.

Mehra teaches a powder coating composition that is non-toxic and edible. The powder coating composition comprises enteric film forming polymer (abstract; and columns 3-4). Thus, it would have been obvious to one of ordinary skill in the art to prepare a coating composition in powder form in view of the teachings of Mehra to obtain the claimed invention. This is because Mehra teaches a dry powder coating that can overcome the disadvantages of the known aqueous coating compositions (column 1), because Mehra teaches a dry powder coating composition that is non-toxic and edible, because Mehra teaches that a dry powder coating composition provides an enteric coating that is less tacky and does not have the odor of ammonium hydroxide, and because Mehra teaches that a dry powder coating composition is known in the art.

Claims 9, 10, 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deshpande et al. US 2004/0028737, in view of Mehra et al. and Kokubo et al. US 4,948,622.

Deshpande is relied upon for the reason stated above. Deshpande does not expressly teach the use of pigment in the coating composition.

Kokubo teaches a coating composition comprising edible dyes, and edible lake pigments (column 3, lines 45-50). Thus, it would have been obvious to one of ordinary skill in the art to modify the coating composition of Deshpande to include the use of edible pigments in view of the teachings of Kokubo to obtain the claimed invention. This is because Kokubo teaches that the presence of pigment in a coating composition is well known in the art.

Response to Arguments

Applicant's arguments filed 06/30/11 have been fully considered but they are not persuasive.

Applicant argues that Example 7 of Deshpande, however, uses 2N NaOH (see para. [0064]), which would be considered an alkalinizing agent excluded from the dry powder composition of claim 1 in the present application. The enteric coatings of examples 5-6 of Deshpande are in a form of an aqueous solution (see paras. [0060] and [0063] on page 4). Nowhere including examples 5-6 does Deshpande disclose a dry powder composition, which is the subject matter of claim 1, and the reference fails to disclose the dry powder composition including methacrylate copolymer of Type C, a

Art Unit: 1615

plasticizer, a detackifier, and opacifier but no alkalinizing agent as claim 1 recites. Thus, claim 1 is distinguished from Deshpande.

However, in response to Applicant's arguments that the use of sodium hydroxide taught by Deshpande is as an alkalizing agent, the Examiner notes that sodium hydroxide is also known in the art as a buffering agent, pH adjusting agent, and/or stabilizing agent. See for example the teaching in Whittle et al. at column 40, lines 14-15. Since the present claims do not recite any specific alkalizing agent, the claims do not preclude sodium hydroxide taught by Deshpande. Further, Applicant's attention is called to Example 5, where Deshpande teaches the use of a coating composition without the use of sodium hydroxide.

Applicant argues that Mehra discloses a dry powder composition including an enteric film forming polymer, detackifier, a viscosity modifier, and an alkalinizing/anti-coagulating agent and optionally, a plasticizer (see coln. 2, lines 33-41). Mehra teaches that the alkalinizing agent "acts as an anti-coalescing or stabilizing agent.., to prevent coalescing or blockage of the spray lines and guns, and the alkalinizing agent also reduces the tackiness of the coating" (see coln. 4, lines 3-7). From the teachings of Mehra, there is no reasonable basis to combine Mehra and Deshpande and form a dry powder composition that does not include an alkalinizing agent, which can increase stability, prevent coalescing or blockage of spray lines and guns, and reduce tackiness of the coating, as claim 1 recites. Accordingly, claim 1 and its dependent claims 2-8, 12-15, and 18 are distinguished from Deshpande in view of Mehra. Similar to claim 1,

Art Unit: 1615

claim 11, which is directed to a process of making a dry powder enteric film coating composition, recites that the dry powder film coating composition includes methacrylate copolymer of Type C, a plasticizer, a detackifier, and opacifier but no alkalinizing agent. Thus for at least the same reasons as discussed for claim 1 above, claim 11 also is distinguished from Deshpande in view of Mehra. Accordingly, this rejection should be withdrawn.

However, similar to the above arguments with respect to Deshpande, Mehra teaches the use of an anti-coalescent agent. Accordingly, the rejection over Deshpande in view of Mehra is maintained.

Applicant argues claims 9-10 and 16, which ultimately depend from claim 1, are distinguished from Deshpande in view of Mehra for at least the same reasons as discussed for claim 1 above. Claim 17, which depends from claim 11, also is distinguished from Deshpande in view of Mehra for at least the same reasons as discussed for claim 11 above. Kokubo discloses a coating of a solid medicament with a hot aqueous dispersion of powdery cellulose and a wax coating with melted wax over the cellulose coating (see abstract, coln. 3, lines 16-25, and coln. 4, lines 56-62). Kokubo, however, fails to disclose an enteric coating and thus fails to disclose a dry powder composition of an enteric coating including no alkalinizing agent as claims 1 and 11 recite. Thus, Kokubo does not remedy the deficiencies of Deshpande and Mehra. Accordingly, this rejection should be withdrawn.

However, in response to Applicant's argument that *Kokubo fails to disclose an enteric coating and thus fails to disclose a dry powder composition of an enteric coating including no alkalinizing agent as claims 1 and 11 recite. Thus, Kokubo does not remedy the deficiencies of Deshpande and Mehra. Accordingly, this rejection should be withdrawn*, Kokubo is cited solely for the teaching of the use of coloring agent and/or dye in a coating composition is known in the art.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:30 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. Tran/
Primary Examiner, Art Unit 1615